

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

A/12

November 30, 1988

Donald J. Bird
Cushman, Darby and Cushman
11th Floor
1615 L Street N.W.
Washington, D.C. 20036

RE: Patent Term Extension
Application for
U.S. Patent No. 4,284,647
Issued: August 18, 1981

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,284,647, issued August 18, 1981, is eligible for patent term extension under 35 USC 156. The period of extension has been determined to be two (2) years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register on May 11, 1988 as follows:

$$\begin{aligned} \text{Period} &= 1/2 (\text{Testing Phase}) + \text{Approval Phase} \\ &= 1/2 (1506) + 813 \\ &= 1566 \text{ days} \end{aligned}$$

Since the regulatory review period began (February 14, 1980) before the patent issued (August 18, 1981), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the determination of the length of the extension period. 35 U.S.C. 156(c) (From February 14, 1980 to August 18, 1981 is 552 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: 2058-552=1506 days). No determination of a lack of due diligence was made. The exception of 35 USC 156(c)(3) does not operate to reduce the period determined above. The limitation of 35 USC 156(g)(6)(c) applies in the present situation because Patent No. 4,284,647 was issued (August 18, 1981) before the date of enactment (September 24, 1984) of 35 USC 156; the date of exemption under Section 505(i) of the Federal Food, Drug and Cosmetic Act involving Ucephan became effective (February 14, 1980), was before the date of enactment, and the product was not approved for commercial marketing or use (December 23, 1987) before the date of enactment. Since the period of extension calculated under 35 USC 156(c) for Patent No. 4,284,647 and Ucephan cannot exceed two (2) years under 35 USC 156(g)(6)(C), the period of extension will be for two (2) years.

In due course, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,284,647, a certificate of extension, under seal, for a period of two (2) years. The rights derived from the patent during the period during which the patent is extended are defined in 35 USC 156(b). Upon issuance of the certificate of extension the following information will be published in the Official Gazette:

U.S. Patent No. 4,284,647, granted
August 18, 1981 to Saul W. Brusilow et al
Owner of Record: The John Hopkins University
Title: Process for Waste Nitrogen Removal
Classification: 514-568
Product Trade Name: Ucephan
Term Extended: 2 years

C.E. Van Horn

Charles E. Van Horn
Deputy Solicitor
Patent & Trademark Office

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Ucephan
FDA Docket # 88E-0104